STATEMENT ON PRIORITY SETTING AND QUANTITATIVE RISK ASSESSMENT

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The National Institute for Occupational Safety and Health (NIOSH) was created under the Occupational Safety and Health Act of 1970 within the Department of Health, Education, and Welfare to act as the research, and standards recommending component of that Act. In the Department of Labor, the Occupational Safety and Health Administration (OSHA) was created to act as the regulatory agency charged with enforcement of the Act. One principle role of NIOSH was to recommend to OSHA and later, under the 1977 Federal Mine Safety and Health Act Amendments, to the Mine Safety and Health Administration (MSHA) criteria for recommended occupational safety and health standards. Since 1972, NIOSH has developed for the Department of Labor approximately 118 documents with recommended standards.

To accomplish this task, a priority system was established to determine what documents to develop. Initially, this system included a ranked list of subjects for documents (developed in 1972). The ranking was determined by multiplying the estimated number of workers exposed by a severity rating, which was assigned by a panel of experts from within and outside the government. This system worked reasonably well because it identified some major hazards that needed to be addressed, however, in the rapidly expanding field of occupational safety and health, new sources of information were evolving, such as the results of the NIOSH National

Occupational Hazard Survey and the National Cancer Institute Carcinogenesis Bioassay Program. With these new sources a more formal priority setting system evolved, and since 1977, this system has contained the following elements:

-- Solicitation inside and outside NIOSH of nominations for Criteria Document subjects;

-- screening of nominations and preparation of internal hazard summaries;

-- requests for information in the Federal Register and other selected sources;

-- preparation of information profiles on the nominated subjects;

-- requests for review and comment on information profiles to NIOSH research divisions and the Department of Labor resulting in grouping of the subjects into high, medium, and low priority categories; and

-- recommendations to and final selection by NIOSH Director of subjects for criteria documentation.

This procedure allowed for more advanced planning than did earlier procedures allowing NIOSH to set priorities three years in advance. To accomplish this, information profiles were developed to outline all available information about a selected subject. Prior to this time, priorities were set using only information that was readily available to those persons participating in the priority setting process.

The existing system had shortcomings, primarily because it was intended to define the Institute research priorities only with regard to document development. Further, some criteria documents were criticized as unnecessary or trivial, for example, the criteria document on carbon dioxide. In addition, the system was an effort to identify criteria document efforts where data were insufficient to complete the project or to permit NIOSH to form meaningful conclusions. The system also did not take advantage of the Institute's current awareness capabilities, such as findings from the Health Hazard Evaluation program or the growing number of methods that were being employed to link existing surveillance systems for evaluating the outcomes related to occupational injury and disease. These methods are continually being refined for use in existing cancer and death registries, insurance and safety survey data bases, as well as other methods.

It must be recognized, when using such systems, that problems which may alter or give misleading results, may occur. For example, the actual risk to selected subgroups within these surveillance systems may remain unobserved when only overall averages of the total systems are analyzed. Determinant criteria may be defined in an insufficient way. Occupation is often times poorly registered on death certificates and in other registries. Frequently the present exposure has little to do with the outcome, especially where long-term effects are concerned. Morbidity by occupation is rarely recorded, except for some largely unavailable systems e.g., Social Security files on morbidity claims. Turnover of workers may alter the exposures and select individuals to different exposures.

The old NIOSH system also failed to suitably integrate the research divisions input into priority setting and standard recommendations. To the research divisions any task that distracted from their prime mission of research was viewed as burdensome.

A new priority system is now emerging. Its goal will be to recommend and document the rationale of priorities for Institute research, document development, and for making recommendations for standards. Two distinct but inter-related objectives are proposed. One objective will be to provide NIOSH management with recommended subjects for documents intended to convey formal NIOSH recommendations including, but not exclusively, recommendations for

occupational standards. A documented master list of priority subjects for the orderly adoption, scheduling, and initiation of document projects will be established. This master list will also provide NIOSH program planners with criteria for the overall evaluation of program plans submitted by the research divisions and thus, through research planning, information gaps can be filled to support eventual document development.

The second objective will be to provide the NIOSH management with documented recommendations for NIOSH intramural and extramural research. The purpose is to assist research divisions in identifying subject areas where new research efforts could provide information useful in ameliorating occupational health hazards, even if the subject is not yet a priority subject for document development. In this way, research divisions would be aware of information gaps, problem areas, and emerging issues. NIOSH program planners can then review (from their management and funding viewpoint) proposed project plans as submitted by the research divisions in the context of the availability of data and future NIOSH needs. This list will also be used to suggest opportunities for inter-divisional collaboration on research.

This new priority setting activity will incorporate all NIOSH surveillance activities to include general industry health and safety risks, as well as mining risks. The product will consist of

five lists. One will be an overall master list of priority subjects for document development. The other four will contain priority subjects for research in field studies; physical sciences and engineering; biological and behavioral studies; and injury. Each list will be accompanied by a set of Priority Rationale Statements, one for each entry. These Priority Rationale Statements will include an information profile and the identification and justification of a document and/or research need. A single subject could conceivably appear on one or more priority lists, in which case multiple Priority Rationale Statements would be prepared, each tailored to the appropriate respective list. The Priority Rationale Statement will provide the user of each list a means of evaluating relative scientific importance while weighing other decision factors such as policy judgements.

Numeric scoring, which is acknowledged to be a crude process, will be used to initially rank subjects taking into consideration workers' exposure, type and severity of affect, gaps in knowledge of subjects, future trends in use or application of the subject, etc. Further information for each of these subjects will then be sought throughout government, academia, labor, and industry from which a refined list of subjects will be developed into information profiles and information gaps analyses will be performed. Based upon these analyses, a final Priority Rationale Statement will be developed on each subject for each of the five general areas. These final

Priority Rationale Statements, with ranked recommendations, will then be used by the Institute management to determine the course of the Institute's standard recommendations and research emphasis. It must be strongly understood that in this system the integration of emerging problems will be considered as they arise.

While the Institute's standard recommendations and research programs need to be coordinated with the regulatory arm of the Occupational Safety and Health Act, the Department of Labor, they should not be solely guided by it. NIOSH should be thinking ahead and developing its programs, not just for present regulatory needs, but for non-regulatory public health recommendations as well as future emerging areas of possible risk to workers. Most recently, NIOSH released recommendations on the possible risks associated with the coal liquefaction process. While the current number of coal liquefaction workers are not large, the future clearly appears to be different, as this and other alternate energy sources are developed. NIOSH should be exploring all areas where workers' health and safety may be in danger and to further weigh these concerns in favor of the individual worker. To do this, the risks must be addressed in a way that accommodates the needs for regulation but that do not limit the role of the Institute. This role is to develop recommendations that will assure to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional

capacity even if such employee has been regularly exposed for the period of his working lifetime. NIOSH has been performing this role in the past, but on an ad hoc basis with no formalized approach.

Previously, a NIOSH standard recommendation was developed using a variety of factors such as the level for which no effects were observed in animals or humans. Most times a safety factor was applied to reduce this level even further to assure that even the most susceptible individual would be given a degree of safety. When dealing with carcinogenic affects, the Institute generally took the approach that no level was safe. This assumption is based in part, on the belief that scientifically there is no way to determine a safe level for substances known to produce cancer in animals. This same belief also led to the 1958 Delaney Amendment which imposes a zero tolerance for carcinogenic food additives. Further support of this principle was stated in the 1970 Ad Hoc Committee Report to the Surgeon General[1] that states, "The principle of a zero tolerance for carcinogenic exposure should be retained in all areas of legislation presently covered by it and should be extended to cover other exposures as well. Only...where contamination of an environmental source by a carcinogen has been proved to be unavoidable should exception be made (and then) only after the most extraordinary justification is presented...Periodic review...should be made mandatory." These principles remained with the Institute program of standard recommendations until the July 2, 1980, landmark

Supreme Court Decision that found OSHA had exceeded its statutory authority by failing to show that the benzene standard was "reasonably necessary or appropriate." The court ruled that section 3(8) of the OSHA Act required OSHA to produce "substantial evidence" which demonstrates that the regulated substance poses a significant risk of material impairment of health and that the new standard would reduce the risk. The "substantial evidence" required by the courts, however, does not have to approach scientific certainty. The court cited section 6(b)5 of the Act to stress that regulation cannot attempt to produce a risk-free workplace by regulating "insignificant" or "acceptable" risks but it left to OSHA the determination of what "significant" or "unacceptable" means.

The District of Columbia Circuit Court of Appeals Decision on August 15, 1980, upheld the lead standard, where acceptable risk was estimated for a material that is not known to be a carcinogen. These decisions provide the impetus for modifying NIOSH's current program to include quantitative risk assessment. For the purposes of this presentation, quantitative risk assessment is defined as an analysis of both the probability and severity of health impairment. It involves an estimate of the likelihood of occurrence of a material impairment of health from the agent, substance, or process on which a health hazard assessment has been performed. This assessment needs to be quantified so that the number of workers likely to suffer this material impairment to their health at each of

one or more relevant exposure levels can be estimated. This definition should be distinct from what is commonly referred to as risk evaluation which incorporates societal judgements with quantitative risk assessment so that the acceptability or significance of the qualified effect is judged. For example, it might be concluded that an irreversible effect (pneumoconiosis or cancer) is acceptable only when it is likely to occur in one of a million workers, whereas, a temporary, fully reversible irritation might be acceptable in one of a hundred workers. It should also be kept in mind that during a working life, a worker might be exposed to numerous carcinogens, co-carcinogens, or promoters, which may have synergistic or additive effects. Under any of these conditions, a mild or weak carcinogenic substance may become a strong or potent carcinogen. This same principle can be true for non-carcinogenic substances as well.

Many federal agencies, both regulatory and non-regulatory, have had experience with quantitative risk assessment and many of them testified before the House of Representatives Subcommittee on Science, Research and Technology on "How Risk Comparison Can Become a Valuable Instrument of the U.S. Regulatory Policy." The prevailing opinion appeared to be that quantitative risk assessment can be useful in establishing priorities and in estimating the reduction in risk as a result of regulatory actions. However, it cannot be used as the sole basis for regulations because of the

uncertainties of the risk assessment process. NIOSH analysis of quantitative risk assessment would tend to enforce this opinion.

Certain aspects of the regulatory statutes provide some guidance regarding the nature of risk assessments that are appropriate as a basis for promulgating regulations. This guidance differs not only from one act to another, but often from one section to another within the same statute. Quantitative risk assessment has been used extensively by the EPA in the promulgation of National Water Quality Standards. USDA, on the other hand, does not conduct risk assessments in the same sense that EPA does. The meat and poultry inspection acts explicitly state that no substance, whatever its benefits, may be added to meat and poultry if the substance poses any risk to human health. CPSC has had experience with both carcinogenic and acute non-carcinogenic quantitative risk assessments; OSHA has only had experience with carcinogenic assessments. The non-threshold linear model has been used most often for quantitative carcinogenic risk assessment, however, various other models have also been used.

NIOSH has evaluated the area of quantitative risk assessment and has made observations relevant to estimating human risk.

Characteristics of toxicological processes which are important, include:

1. Biological reversibility or irreversibility of the process,

2. potential cumulative nature of the process,

3. possibility for a progressive nature of the process,

4. rates of absorption, metabolism, de-toxification, excretion and related processes,

5. biochemical processes (e.g., receptor occupation, alkylation, repair, enzyme induction, etc.),

6. changes in homeostatic mechanisms such as hormonal balances and cellular immunity,

7. genetic and non-genetic variation among individuals, and

8. temporal variables (e.g., aging and experimental variables).

Since human epidemiologic studies accommodate these variables, quantitative risk assessment will be most accurate when based on human data. When epidemiologic data is insufficient for risk estimation, extrapolation of data from other species, requiring assumptions on the quantitative toxicologic relationships among species, must be made. Since extrapolation entails projection beyond the known, based on assumed continuity, correspondence or

other parallels, a source of uncertainty is introduced into the risk assessment process. Minimizing the uncertainty requires the use of objective criteria whenever possible. Mathematical formulas should be sought for each facet of the extrapolation in order to state clearly and precisely the logical implications of the model. In addition, the calculated results from the formulas must be carefully scrutinized for consistency with the available human data.

At least three different types of extrapolations may be necessary to estimate quantitative human risk. These extrapolations are: (1) from higher doses to lower doses, (2) from lower species to man, and (3) from controlled laboratory conditions to the diverse human environment. Central to each of these extrapolations is the nature of the dose-response relationships and biochemical mechanisms of action of the agent. The process of developing extrapolative models of toxicologic processes can be divided into three identifiable phases. The first phase is a description of the fundamental processes. Then symbols are assigned to these processes and a mathematical formula is derived which seeks to link the dose to the response. Finally, the predictions derived from these formulas are evaluated against the initial objective description and assumptions.

Species-to-species extrapolations are based on the fundamental assumption that similar toxicity mechanisms exist in both species. A critical point-by-point comparison of the signs and symptoms of

toxicity in the test species with available human evidence would contribute to the subjective persuasiveness of the extrapolation. Three objective species-to-species extrapolation factors should be considered; relative dosage, metabolism, and sensitivity. Correction for dosage can be accomplished by methods such as adjusting for respiratory rates of metabolic pathways, which requires some assumption about the nature of the "active metabolite." Insight into the relative species sensitivity of model systems may be obtainable from an evaluation of comparable data.

Extrapolation from controlled laboratory conditions to human exposure conditions may need consideration of additional factors unique to humans in the occupational environment. Evaluation of the potential influence of other factors, such as alcohol, heat, smoking, stress, etc. on the anticipated dose-response relationships should be performed. The evidence on the interaction between smoking and asbestos, alcohol and dimethylformamide, is indicative of the importance of considering non-occupational factors where assessing risk. Quantitative models should be developed for these types of interactions.

The application of quantitative models to the two broad classes of toxic effects, reversible (i.e., irritation, CNS depression, etc.) and irreversible (carcinogenesis, mutagenesis, teratogenesis, chronic organ damage, etc.) require the use of different models.

Reversible effects may be modeled with empirical pharmacologic relationships derived from receptor theory, which usually generates a threshold. The modeling of irreversible effects is in a state of controversy and flux.

Two general classes of mechanisms have been proposed for carcinogenesis, threshold and non-threshold. Threshold postulates appear to be derived from empirical biological data rather than quantitative mathematical models.

Several non-threshold models have been proposed. In 1950, Iversen and Anley[2] proposed a quantitative model of carcinogenesis based on the occurrence of a single irreversible event (hit theory). Shortly thereafter, a number of investigators noted that the death rate for many forms of human cancer increased proportionately with the fifth or sixth power of age.[3,4,5] Since the data were considered consistent with an incidence rate proportional to the fifth or sixth power of the duration of exposure to an agent at a constant concentration, two plausible explanations of the power law were generated. Fisher and Holloman[3] proposed that five or six different cells be transformed into a single tissue in order to form a tumor. Alternatively, five or six changes in a single cell were proposed by Nordling.[4] These multi-hit or multi-stage models are consistent with both the biological irreversibility of the process and the cumulative nature of the process.

The single hit theory is the simplest possible stochastic model which relates dose to response. A hit, the fundamental process, is believed to transform a normal cell into a malignant cell. The expected number of hits or transformations is assumed to be directly proportional to the dose.

Another mathematical approach to modeling carcinogenesis is the log-probit model. Underlying the use of the log-probit model is the assumption that the individual differences in biologic response are due to log-normally distributed degrees of sensitivity of the exposed population. The probit model plots the log of the dose against the probit of the response where the probit transformation is an exponential function. This model tends to predict lower degrees of risk than the stochastic models (single or multi-stage). The probit model considers the heterogeneity of populations.

Several types of biochemical models have been proposed for use in risk estimation. Ehrenberg[6] suggested risk estimates should be derived from the amount of covalent binding to DNA. Cornfield[7] proposed extrapolating on the basis of competitive chemical processes in the mechanism. Gehring, et al[8] have combined pharmacokinetics with covalent binding to predict the dose-response characteristics of the metabolically activitated carcinogen, vinyl chloride. Gillette[9] has modeled the kinetics of formation of

biologically reactive intermediates which may initiate adverse toxicologic processes. Biochemical and pharmacodynamic modeling is advancing rapidly since several types of experimental data can be incorporated directly into the model. Compared to other models, the use of biochemical models more efficiently uses a comprehensive data base. The unavailability of data frequently limits the use of biochemical models.

NIOSH's approach to quantitiative risk assessment will be predicated on the idea that the reliability of such an assessment substantially depends on the adequacy of the information available. The types of necessary information fall into several categories which include exposure patterns, chemical and biological relationships, experimental toxicity and epidemiologic studies. Exposure patterns should include an evaluation of the points of potential exposure of workers to chemical or physical agents. An estimation of the size of the exposed worker population and the degree of exposure in various occupational environments should be included. For a chemical agent, the evaluation should include at least: Tracing the agent through its manufacture, transport, storage and use; identifying unusual uses or worker practices that could subject a particular subgroup of workers to dangerous exposures; determining if a chemical agent is used as a component in another product and tracing potential exposures attendant to the use of such a mixture; examining the potential for antagonists; additive or synergistic

actions with other agents likely to be present; identifying additional exposures to the agent outside the occupational environment; and discussing the methods and uncertainty inherent in any estimates made. Similarly, when physical agents or processes are studied, appropriate evaluations should be made.

Chemical and biologic relationships should summarize information on biotransformation (transport, metabolic fate including intermediary biotransformation products and excretion). When possible, structured activity relationships with related compounds should be included. Such a discussion should also compare the toxic mode and mechanisms of action, to the extent known, in the various species and strains of animals.

Relevant toxicity studies should be summarized and presented with a critical evaluation of the merit of each study with consideration to the adequacy of the experimental design, to the quality of the experimental data, to the suitability of the controls (matched, historical, and positive) to the interpretation of the data, and to the reliability of the conclusions. If an experiment is rejected for use in the risk assessment, a justification must be provided.

Available epidemiologic studies should be summarized and presented with critical evaluation of the merit of each study with consideration to the criteria outlined in the IRLG Guidelines for

Documentation of Epidemiologic Studies.[10] These guidelines recommend that the following topics be discussed: Scientific background and objectives of the study; study design, with a description of the population from which the study subjects were selected and methods of selection; detailed description of comparison subjects and methods of selection; data collection procedures used, and description of the analytical methods and statistical procedures employed including the power of the study and the confidence intervals of the risk estimates. The availability of published reviews should be noted and, where appropriate, the reviews should be discussed. The limitations of each study with respect to risk assessment should be explicitly stated. If a study is to be rejected for use in the quantitative risk assessment, reasons for doing so should be given. However, human data, even if inadequate for a characterization of the actual magnitude of risk, should be included in the health risk assessment. Such data could be helpful in interpreting animal responses to human sensitivity.

NIOSH believes that no matter if the quantitative risk assessment is from epidemiologic or animal data methodological problems can arise. This is due to the need to extrapolate from effects observed in a specific population under one set of exposure conditions to an estimate of the effects in the worker population. Because of the uncertainties involved with these extrapolations and the public health consequences, NIOSH, as well as the IRLG Working Group on

Risk Assessment favors the policy of making cautious assumptions whenever they are needed to conduct a risk assessment. For example, the IRLG has stated that using the linear non-threshold dose response model to evaluate the risk from carcinogens is consistent with this policy. They have concluded that this model has an adequate scientific basis and is less likely to understate risk then other plausible models. NIOSH's quantitative risk assessment effort should always attempt an extrapolation, such as the linear non-threshold model for carcinogens, which it views as the least likely to underestimate risk. Extrapolation with multi-variable models, which would attempt to add mathematical and biological refinements, should also be attempted in order to obtain the best possible estimates of the true human risk.

NIOSH also believes that comparative risk analysis should be made to compare health risks associated with one course of action to those of alternative courses of action. This comparative risk analysis may include:

-- Comparisons of one particular action with no action at all;

— comparisons of risks due to decisions to control contaminants in the environment at different levels; and

— comparisons of the risk of any course of action to a range of risks which are present in the occupational environment.

If other quantitative risk assessments are available on the same agent, substance or process, these assessments should be compared to the present assessment. This discussion should include a comparison of the data used, the assumptions made, the mathematical models employed, the resulting risk estimates, the populations for which applicable and the reliability of the estimates.

It is expected that the data required for a risk assessment will usually be a subset of the total data collected for a given project. When the data are sufficiently strong, risk assessments may be used to support regulatory activities. However, less complete data sets, unsuitable for standards setting, can often provide sufficient information for risk assessments in support of other activities, such as developing priorities or indicating new areas for research. The recommendation to apply risk assessment techniques to projects dealing with any material impairment to health is meant to include all types of health hazards, not just cancer. In non-regulatory projects, risk assessment can be a useful tool for decision making.

Finally, quantitative risk assessment, as defined earlier, is a process that may be characterized as a value-free objective undertaking. In order to help assure the scientific objectivity of this understanding, the potential economic and political consequences of the risk assessment must not be allowed to influence the conclusions.

Risk evaluation, on the other hand, is a value-laden activity that must be responsive to the views of government at all levels, business enterprises, labor unions, public opinion and a host of other interests including the international community.

With these differences delineated, it is apparent that both are best achieved by keeping the assessment and evaluation function organizationally independent, an approach consistent with the intent of the Occupational Safety and Health Act of 1970. NIOSH provides the quantitative risk assessment and OSHA the risk evaluation.

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15. Supplementary Notes

16. Abstract (Limit: 200 words) This testimony discussed a new priority system emerging at NIOSH for the recommendation and documentation of the setting of priorities for NIOSH research, document development, and for making recommendations for standards. Two interrelated and yet distinct objectives were served by the priority system. First was the objective to provide NIOSH management with recommended subjects for documents intended to convey formal NIOSH recommendations including, but not exclusively limited to, recommendations for occupational standards. A documented list will be established which will contain priority subjects for the orderly adoption, scheduling, and initiation of document projects. This list will provide NIOSH planners with criteria for the overall evaluation of program plans submitted by various researchers. The second objective was to provide the NIOSH management with documented recommendations for NIOSH intramural and extramural research, assisting research divisions in identifying subject areas where new research efforts would provide useful information to ease occupational health hazards. This new priority setting will incorporate all NIOSH surveillance activities including general industrial health and safety risks, as well as mining risks. The development of criteria standards based on this type of priority setting was outlined. Extrapolations which will be necessary to estimate quantitative human risk were described.

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